No. 24-1187

# In the Supreme Court of the United States

VANDA PHARMACEUTICALS, INC., PETITIONER

*v.*

FOOD AND DRUG ADMINISTRATION, ET AL.

*ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT*

## BRIEF FOR THE RESPONDENTS IN OPPOSITION

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## QUESTION PRESENTED

Whether the Food and Drug Administration properly denied fast-track status to petitioner's drug tradipitant to treat gastroparesis.

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### OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-22a) is reported at 123 F.4th 513. The opinion of the district court (Pet. App. 23a-58a) is available at 2023 WL 6035663.

### JURISDICTION

The judgment of the court of appeals was entered on December 17, 2024. On March 12, 2025, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including May 16, 2025, and the petition was filed on that date. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

### STATEMENT

1. Before being sold and marketed in the United States, new drugs generally require approval from the Food and Drug Administration (FDA) based on FDA's conclusion that the drug is safe and effective for each of its intended uses. 21 U.S.C. 355(a) and (d). Applications

for approval must include reports of the clinical testing done on humans. 21 C.F.R. 314.50(d)(5). Before such testing may begin, the drug's sponsor must typically conduct non-human studies that establish to FDA's satisfaction that a human study would be "reasonably safe." 21 C.F.R. 312.23(a)(8); see 21 U.S.C. 355(i). "At any time" during the research process, FDA may issue a "clinical hold" barring further studies. 21 U.S.C. 355(i)(3)(A). Among other circumstances, FDA may issue a clinical hold if it concludes that it lacks "sufficient information * * * to assess the risks to subjects of the proposed studies." 21 C.F.R. 312.42(b)(1)(iv); see 21 U.S.C. 355(i)(3)(B)(ii); 21 C.F.R. 312.42(b)(2)(i).

Congress has created various incentives for drugs intended to fill unmet treatment needs. See 21 U.S.C. 356. This case involves the fast-track program, which is available on request for a drug that is intended "for the treatment of a serious or life-threatening disease or condition," which "demonstrates the potential to address unmet medical needs for such a disease or condition." 21 U.S.C. 356(b)(1).

If fast-track status is granted, the statute instructs FDA to "take such actions as are appropriate to expedite the development and review of the application for approval" of that drug. 21 U.S.C. 356(b)(3). FDA guidance explains that fast-track status offers "frequent interactions with the [FDA] review team" and the possibility of "[r]olling [r]eview" of the new-drug application. C.A. App. 672-673; see 21 U.S.C. 356(d)(1). Fast-track status also offers the possibility of "priority review" of the final application "if supported by clinical data." C.A. App. 672.

2. Petitioner is a pharmaceutical company that is developing the drug tradipitant to treat a chronic stomach

condition called gastroparesis. Pet. App. 5a. In 2016, FDA permitted petitioner to conduct a four-week human study of tradipitant based on existing short-term studies in dogs and rats. 436 F. Supp. 3d 256, 262.

In April 2018, petitioner sought to extend its four-week trial by 12 months. Pet. App. 6a. FDA denied the proposal, determining that petitioner did not offer sufficient evidence to assess the risk of longer-term human trials. *Ibid.* After petitioner repeatedly refused to conduct a nine-month animal study that could have supplied that evidence, or an adequate alternative study, FDA imposed a partial clinical hold barring human studies longer than 12 weeks. *Id.* at 6a, 31a. Petitioner unsuccessfully challenged that hold in district court, where the court agreed with FDA that there was "no question as to the scientific basis for the hold." 436 F. Supp. 3d at 264. Petitioner did not appeal.

3. In 2021, petitioner filed the request for fast-track status at issue here. Pet. App. 7a. In its request, petitioner described gastroparesis as a "chronic" condition requiring "long-term medications." *Ibid.* (citation omitted).

FDA denied petitioner's request. Pet. App. 7a. FDA agreed that "gastroparesis is a serious condition with an unmet medical need." *Ibid.* But without long-term studies—or any ability to conduct long-term studies—petitioner could not show that its product had the "potential" "to treat the symptoms of gastroparesis, which are chronic." *Ibid.* As the government explained and petitioner did "not appear to question" in district court, FDA did not treat the clinical hold as per se dispositive. *Id.* at 45a & n.4; contra Pet. 13-14, 23, 35. Instead, a contemporaneous internal FDA memorandum noted other "issues with [petitioner's] study's methodology,"

Pet. App. 7a, which made petitioner's data "difficult to interpret," C.A. App. 333. Those concerns "mirror[ed] feedback" that FDA had earlier provided to petitioner. Pet. App. 8a.

4. In May 2022, petitioner filed this lawsuit in the United States District Court for the District of Columbia alleging that FDA's denial of fast-track status for tradipitant violated the Administrative Procedure Act. Compl. ¶¶ 127-154. The parties cross-moved for summary judgment, which the district court granted to the government. Pet. App. 23a-58a.

The district court concluded that FDA properly considered the partial clinical hold in denying petitioner's application. Pet. App. 41a-49a. As the court noted, the fast-track statute requires a drug's sponsor to show that the drug has the "potential" to meet an unmet medical need. *Id.* at 46a (quoting 21 U.S.C. 356(b)(1)). Here, FDA reasonably identified the relevant need as "therapies . . . for the chronic treatment of the core signs and symptoms of gastroparesis." *Id.* at 45a (citation omitted). And FDA reasonably determined that, to meet that need, a drug would need to be "safe and effective" since there is no "unmet medical need for therapies that are ineffective or unsafe." *Id.* at 43a-44a.

The key question was thus whether tradipitant had the "potential" to offer a safe and effective treatment for chronic (*i.e.*, long-term) gastroparesis. As the district court observed, the word "'potential'" is "inherently prospective—it refers to that which is '[n]aturally and probably expected to come into existence at some future time, though not now existing.'" Pet. App. 46a (quoting "Potential," *Black's Law Dictionary* 1168 (6th ed. 1990)). To determine whether tradipitant had such a potential, FDA could "reasonably consider * * *

tradipitant's development plan." *Id.* at 47a. Applying "a fact-specific inquiry," FDA properly determined that, "in the circumstances of this case, the partial clinical hold limited the agency's ability to assess whether tradipitant had the potential to address an unmet medical need." *Id.* at 44a-45a. Petitioner therefore could not establish its statutory entitlement to fast-track status. *Id.* at 45a.

The district court also rejected a series of arbitrary-and-capricious challenges that petitioner has not renewed here. Pet. App. 49a-57a.

5. In December 2024, the court of appeals affirmed. Pet. App. 1a-22a. The court first rejected the government's argument that the case had been mooted by subsequent developments. *Id.* at 11a-14a. The government contended that petitioner would no longer benefit from fast-track status because, while the litigation was pending, petitioner submitted its new-drug application, which FDA declined to approve in present form. *Id.* at 12a. In the court's view, those events did not establish mootness because fast-track status could still give petitioner some advantages in ongoing discussions with FDA. *Id.* at 12a-14a. In the alternative, the court applied the mootness exception for cases capable of repetition yet evading review. *Id.* at 14a.

On the merits, the court of appeals upheld FDA's decision. Pet. App. 14a-22a. The court agreed with FDA and the district court that petitioner's challenge rested on "an untenable distinction" between a drug and its development program. *Id.* at 15a. As the court explained, "[t]he best reading of the statute indicates that * * * Congress intended to benefit drugs that are not yet fully effective but that can demonstrate their potential effectiveness in addressing an unmet medical need in

the future." *Id.* at 17a. The text "mandates an inherently prospective analysis" by asking FDA to assess whether a drug "has the 'potential' to address" unmet medical needs. *Id.* at 16a. In answering that question, the "drug's development plan, including what past and future studies may demonstrate about the potential of the drug, are plainly relevant and permissible considerations." *Ibid.*

Here, FDA had conveyed "numerous concerns" about petitioner's data that petitioner refused to correct by conducting additional studies. Pet. App. 17a. Petitioner therefore "could not demonstrate tradipitant's potential to address the unmet need that [its] application identified." *Ibid.* And, having "fully litigated the propriety of the clinical hold" and lost, petitioner was "estopped" from collaterally attacking the hold now. *Id.* at 21a. FDA therefore reasonably denied petitioner's application "consistent with the statute's mandate." *Id.* at 17a.

The court of appeals also affirmed the district court's rejection of petitioner's arbitrary-and-capricious challenges, observing that FDA reasonably limited its review to the "long-term symptoms of gastroparesis," consistent with petitioner's own filings. Pet. App. 18a; see *id.* at 19a-22a.

## ARGUMENT

Petitioner contends (Pet. 16-32) that the court of appeals misinterpreted the statute and gave undue deference to FDA in upholding the denial of fast-track status for tradipitant. Further review of that contention is unwarranted. The decision below is correct and does not conflict with any decision of this Court or any other court. And this case would be a poor vehicle to review the question presented because, at this point in the

drug-development process, fast-track status would offer few, if any, benefits to petitioner.

1. The court of appeals correctly upheld FDA's denial of fast-track status for tradipitant. By statute, FDA shall grant fast-track status "at the request of the sponsor" if the drug "demonstrates the potential to address unmet medical needs." 21 U.S.C. 356(b)(1). As the court of appeals explained, that text "places the burden on an applicant to 'demonstrate' that its drug meets the fast track criteria." Pet. App. 15a. And the word "'potential'" "mandates an inherently prospective analysis." *Id.* at 16a (citing "Potential," 12 *Oxford English Dictionary* 224 (2d ed. 1989)). The "best reading of the statute" therefore extends fast-track status to "drugs that are not yet fully effective but that can demonstrate their potential effectiveness in addressing an unmet medical need in the future." *Id.* at 17a. As part of that inquiry, "[t]he drug's development plan, including what past and future studies may demonstrate about the potential of the drug, are plainly relevant and permissible considerations." *Id.* at 16a. A drug with no apparent path to addressing the actual patient needs identified by the fast-track request lacks the "potential" to meet those needs. 21 U.S.C. 356(b)(1).

FDA reasonably determined that petitioner failed to meet that statutory standard. As the court of appeals observed, petitioner's "own filings with the FDA" emphasized "that gastroparesis is a chronic disease," which already has an "FDA-approved short-term treatment." Pet. App. 18a. FDA therefore reasonably defined "the unmet medical need" as the "long-term treatment of gastroparesis symptoms." *Ibid.*

Petitioner failed to show that tradipitant had the potential to meet that long-term need. FDA identified

"numerous concerns" with petitioner's "existing data," which required FDA to evaluate "whether future studies might cure those problems." Pet. App. 17a. But petitioner could not conduct long-term human studies, because it refused to conduct the additional non-human studies needed to demonstrate that long-term human studies would be safe. *Ibid.* Absent some way to collect the necessary data, petitioner "could not demonstrate tradipitant's potential to address the unmet need that [petitioner's] application identified." *Ibid.*

2. a. Petitioner contends (Pet. 18) that FDA impermissibly considered "the drug's development program" because the statute "unambiguously focuses" on "the chemical, molecular entity being studied by a drug sponsor." Because the chemical compound that forms tradipitant, in petitioner's view (Pet. 24), has the "potential" to address patient's needs, the "current regulatory hurdles" to tradipitant's development should be irrelevant.

That argument is flawed on at least two levels. *First*, petitioner's effort to distinguish a drug from its development program is "untenable." Pet. App. 15a. As petitioner's dictionary definitions make clear, "'potential' refers to something that can develop or become *actual* in the future." Pet. 19 (emphasis added). The text therefore directs FDA to consider real-world possibilities, not abstract hypotheticals. A champion distance runner lacks the "potential" to win this year's Boston Marathon if she is subject to a one-year ban for doping. So too a drug that lacks a viable path to development does not have the "potential" to meet an unmet medical need. On petitioner's view, FDA would be required to prioritize a drug that could never be tested in humans—say, because non-human testing reveals widespread le-

thal side effects—simply because the chemical compound has the abstract possibility of addressing an underserved condition.

*Second*, petitioner is factually mistaken (Pet. 21-23) that tradipitant's potential would be irrefutable but for the clinical hold. Petitioner highlights what it calls (Pet. 21) "a well-controlled 4-week clinical study." But FDA noted multiple "issues with [petitioner's] study's methodology," not limited to the lack of long-term data. Pet. App. 7a. For example, petitioner included results that were "not statistically significant." C.A. App. 333. And petitioner allowed human subjects to use other medications—a potential confounding variable that made the results "difficult to interpret." *Ibid.* While some participants in that study later lauded their experiences to FDA in a citizen petition (Pet. 22), that unscientific self-reporting long postdates the decision at issue and is of questionable relevance regardless.

Petitioner emphasizes one sentence in a ten-page letter denying petitioner's application for a different FDA program where an FDA official said that she saw "a potential therapeutic role for tradipitant, particularly for short-term relief of nausea." Pet. 3, 13, 21 (quoting C.A. App. 657). Petitioner omits that the official requested "additional data." C.A. App. 657. Regardless, the official focused on short-term benefits, but petitioner does not challenge the court of appeals' conclusion that FDA reasonably read its fast-track request to focus on long-term treatment. Pet. App. 18a.

Petitioner also notes (Pet. 3, 21-22) that FDA has allowed a handful of patients with no alternative treatment options to use tradipitant. As the court of appeals explained, that program is "governed by a different statutory standard" and is "wholly unrelated" to fast-

track status. Pet. App. 20a. While petitioner may disagree with FDA's analysis of the scientific data, that factual dispute does not evidence any error in the court of appeals' interpretation of the statute.

b. Petitioner also accuses the lower courts of "abandoning their obligation to 'exercise their independent judgment'" and "resurrect[ing]" the overruled deference framework of *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Pet. 16-17 (quoting *Loper Bright Enters.* v. *Raimondo*, 603 U.S. 369, 412 (2024)).

That account misreads the decisions below. Citing *Loper Bright*, the court of appeals acknowledged its obligation to identify "the 'best reading' of the statute." Pet. App. 10a (quoting *Loper Bright*, 603 U.S. at 395). The court applied an ordinary-meaning approach, looking up the key term ("potential") in a contemporaneous dictionary and seeking context clues in other statutory provisions. *Id.* at 16a-17a. The district court employed a similar methodology, using many of the same dictionaries as petitioner. Compare *id.* at 46a-47a, with Pet. 19. Nothing in that interpretive analysis harks the resurrection of *Chevron*.

Petitioner quotes snippets from two sentences at the end of the court of appeals' statutory analysis, which petitioner says reflect an "anachronistic approach to statutory construction." Pet. 17; see Pet. i, 4, 15-16, 30. In full, those sentences state:

> In the face of [the] issues with existing data, the agency's consideration of whether future studies might cure those problems is entirely consistent with the statute's mandate. It was equally reasonable for the FDA to conclude that Vanda's decision not to conduct additional studies required

> to lift the partial clinical hold meant that Vanda would not cure those issues and, thus, could not demonstrate tradipitant's potential to address the unmet need that Vanda's application identified.

Pet. App. 17a.

In context, those sentences reflect the court of appeals' application of the statutory standard—which it ascertained for itself in the preceding pages—to the facts at hand. In so doing, the court properly deferred to FDA's judgment that petitioner's evidence did not demonstrate the potential to meet unmet medical needs. As this Court observed in *Loper Bright*, in "a case involving an agency," "the statute's meaning may well be that the agency is authorized to exercise a degree of discretion." 603 U.S. at 394. And this Court has subsequently explained that an agency may be "better equipped to assess what facts are relevant to the agency's own decision than a court is." *Seven Cnty. Infrastructure Coal.* v. *Eagle County*, 145 S. Ct. 1497, 1512 (2025). The court of appeals' decision is fully consistent with this Court's precedent. Having interpreted the statute for itself, the court properly deferred to the FDA's scientific judgment that petitioner's studies did not satisfy that standard.

3. This case does not satisfy the traditional criteria for this Court's review. Petitioner principally contends that the court of appeals misinterpreted the fast-track provision, 21 U.S.C. 356(b). But petitioner does not identify any circuit split on that question, which is unsurprising since the district-court and court-of-appeals decisions below appear to be the only two decisions to interpret that provision since its enactment in 1997.

Petitioner itself recognizes (Pet. 35) that the issue is "vanishingly rare"; this case is apparently the first to

challenge the denial of fast-track status. Accord Pet. 32. Petitioner attributes (Pet. 33-36) that paucity to pharmaceutical companies' fear of FDA and lauds the importance of fast-track status. But whatever the reason for the lack of cases, this statutory-interpretation question that has arisen only once in 28 years is an unsuitable candidate for this Court's review.

Petitioner also urges review (Pet. 32-33) by claiming that the court of appeals reanimated a form of *Chevron* deference. As explained, that contention misreads the decision below, which applied ordinary interpretive tools to reach an ordinary interpretive result. In any event, petitioner does not identify any broader misapprehension of *Loper Bright*. Petitioner just contends that the D.C. Circuit misapplied *Loper Bright* to this particular case. That kind of "error correction * * * is outside the mainstream of the Court's functions and, generally speaking, not among the 'compelling reasons'" that could justify a grant of certiorari. Stephen M. Shapiro et al., *Supreme Court Practice* § 5.12(c)(3), at 5-45 (11th ed. 2019).

4. In any event, this case would be a poor vehicle to address the question presented because developments after the court of appeals' decision confirm that petitioner would no longer benefit from fast-track status. As noted, while this case was pending before the D.C. Circuit, FDA declined to approve petitioner's new-drug application in present form. Pet. App. 12a; see Gov't C.A. 28(j) Letter (Sept. 20, 2024). At that point, petitioner had three options: (1) withdraw the application, (2) submit a revised version addressing FDA's concerns, or (3) request a hearing. 21 C.F.R. 314.110(b).

After the court of appeals' decision, petitioner requested a hearing. Vanda Pharmaceuticals Inc., *Writ-*

*ten Notice of Participation and Request for Hearing*, FDA Doc. No. 2024-N-5933-0001 (Jan. 26, 2025), https://perma.cc/4KB9-TZMD. At the end of the administrative process, FDA will either approve or deny a new-drug application, and a drugmaker may seek court-of-appeals review of an adverse decision. 21 U.S.C. 355(d) and (h). Either way, there is nothing left to fast track. Whether or not the case is technically moot, that lack of practical significance for petitioner would make this Court's review especially unwarranted.

## CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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